DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2260. Adulteration and misbranding of sodium salicylate ampuls. U. S. v. The Intra Products Co., Claude B. Murdock, and Scott A. Powell. Pleas of guilty. Fines of $800 against the company, $400 against Claude B. Murdock, and $1,000 against Scott A. Powell. (F. D. C. No. 23243. Sample No. 48560–H.)

INFORMATION FILED: September 29, 1947, District of Colorado, against the Intra Products Co., a corporation, Denver, Colo., Claude B. Murdock, president of the corporation, and Scott A. Powell, chemist for the corporation.

ALLEGED SHIPMENT: On or about December 13, 1946, from the State of Colorado into the State of Texas.

LABEL, IN PART: (Box) "10 cc. Intravenous Solution Each 10 cc. Contains: Sodium Salicylate 15.4 gr."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Salicylate," a drug the name of which is recognized in the National Formulary, an official compendium, but its strength, quality, and purity fell below the standard set forth in that compendium since the article yielded not more than 52 percent of the labeled amount of anhydrous sodium salicylate and since it contained undissolved material. The National Formulary provides that *ampuls of sodium salicylate* shall yield not less than 95 percent of the labeled amount of sodium salicylate and must be substantially free of undissolved material. The difference in the strength, quality, and purity of the article from the official standard was not stated on its label. Further adulteration, Section 501 (c) (2), ampuls containing a mixture of sodium salicylate and sodium iodide had been substituted for *ampuls of sodium salicylate*.

Misbranding, Section 502 (a), the label statement "Each 10 cc. Contains: Sodium Salicylate 15.4 gr." was false and misleading, since each 10 cubic centimeters of the article contained less than 15.4 grains of sodium salicylate. (The ampuls contained 8.01 grams of sodium salicylate and 8.28 grams of sodium iodide per 10 cc.)

DISPOSITION: October 21, 1947. Pleas of guilty having been entered, the court imposed fines of $800 against the corporation, $400 against Claude Murdock, and $1,000 against Scott Powell.

2261. Adulteration and misbranding of water for injection. U. S. v. Morton G. Falk (Estro Chemical Co.). Plea of guilty. Fine, $500. (F. D. C. No. 14310. Sample Nos. 63531–F, 79917–F.)

INFORMATION FILED: August 17, 1945, Southern District of New York, against Morton G. Falk, a member of a partnership trading as the Estro Chemical Co., New York, N. Y.

ALLEGED SHIPMENT: On or about April 28 and June 1, 1944, from the State of New York into the States of Georgia and Maryland.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not free from pyrogens, as required by the standard, but contained pyrogens; it was not a clear liquid, as required by the standard, but contained undissolved material; and the difference in quality and purity of the article from the standard was not plainly stated, or stated at all, on its label.

Misbranding, Section 502 (a), the label statement "Water for Injection U. S. P. XII" was false and misleading, since the article did not consist of water for injection complying with the requirements of the United States Pharmacopoeia; and the statement "Pyrogen Free" borne on the label of the shipment of June 1, 1944, into Maryland, was false and misleading, since the article was not free from pyrogens.

DISPOSITION: April 3, 1947. A plea of guilty having been entered, the court imposed a fine of $500.

2262. Adulteration of physiological salt solution. U. S. v. 37 Cartons * * *. (F. D. C. No. 24292. Sample No. 10301–K.)

LIBEL FILED: January 6, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about October 28, 1947, by Brewer & Co., Inc., from Worcester, Mass.

PRODUCT: 37 cartons, each containing 5 20-cc. vials, of *physiological salt solution* at New York, N. Y.

LABEL, IN PART: "Physiological Salt Solution (Isotonic Solution of Sodium Chloride, USP.) Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be a drug, "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard. The article was contaminated with undissolved material, whereas the Pharmacopoeia provides that injections must be substantially free from undissolved material.

DISPOSITION: January 20, 1948. Default decree of condemnation and destruction.

2263. Adulteration of epinephrine hydrochloride injection. U. S. v. 60 Vials * * *. (F. D. C. No. 23180. Sample No. 66326–H.)

LIBEL FILED: June 9, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 18, 1947, by Lederle Laboratories, Inc., from Pearl River, N. Y.

PRODUCT: 60 vials of *epinephrine hydrochloride injection* at Philadelphia, Pa.

LABEL, IN PART: "Epinephrine hydrochloride Injection U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Epinephrine Hydrochloride Injection," a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard, since it was contaminated with undissolved material.

DISPOSITION: July 23, 1947. Default decree of condemnation and destruction.

2264. Adulteration of Betathine-S (Super B Complex). U. S. v. 64 Vials * * *. (F. D. C. No. 23962. Sample No. 20814–K.)

LIBEL FILED: November 7, 1947, District of Kansas.

ALLEGED SHIPMENT: On or about October 19, 1947, by Burton-Lewis, Inc., from St. Joseph, Mo.

PRODUCT: 64 vials of *Betathine-S (Super B Complex)* at Topeka, Kans.

LABEL, IN PART: "15 cc. Vial Betathine-S (Super B Complex) * * * For intramuscular or intravenous use."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since it was represented to be for intravenous use and contained undissolved material, whereas an article which is represented to be for intravenous use should be free from undissolved material.

DISPOSITION: January 14, 1948. Default decree of condemnation and destruction.

2265. Adulteration and misbranding of estrogenic hormone. U. S. v. Hormorgano Corporation and Herman Meyer. Pleas of guilty. Fines, $200 against each defendant. (F. D. C. No. 17868. Sample No. 3823–H.)

INFORMATION FILED: March 17, 1947, Eastern District of New York, against the Hormorgano Corporation, Jamaica, N. Y., and Herman Meyer, president and secretary.

ALLEGED SHIPMENT: On or about January 31, 1945, from the State of New York into the State of Pennsylvania.

NATURE OF CHARGE: Adulteration, Section 501 (d), crystalline estradiol and crystalline estrone had been substituted in part for "Estrogenic Hormone Obtained from Pregnant Mares' Urine, Consisting Principally of Estrone and Estradiol," which the article purported and was represented to be.

Misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium, but was fabricated from two or more ingredients; and its label failed to bear the common or usual name of each active ingredient, in that the designation "Estrogenic Hormone," borne on the